Exactech® Acapella™ One Cervical Spacer System
Traditional 510(k)

510(k) Summary

FEB 12 2014

Company:	Exactech, Inc 2320 NW 66th Court Gainesville, FL 32653
Date:	February 10, 2014
Contact Person:	Patrick Hughes Senior Regulatory Affairs Specialist Phone: (352) 327-4762 Fax: (352) 378-2617
Proprietary Name:	Exactech® Acapella® One Cervical Spacer System
Common Name:	Interbody Spacer
Classification Name:	21 CFR 888.3080 Intervertebral Fusion Device with Integrated Fixation, Cervical Class II
Product Code:	OVE

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- K103655 - Octane-C Interbody Fusion System
- K082801 – US Spine Phantom Plus Cage
- K113559 - LDR ROI-C Cervical Cage Implant – Lordotic
- K082270 – Octane-A Interbody Fusion System (material composition only)

Device Description

The Acapella One Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK (polyetheretherkeytone) implant cage with tantalum radiographic markers and two titanium alloy internal anchors. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints, and lordotic angles to accommodate varying anatomical conditions. The device features a chamber intended to be filled with autogenous bone graft material. The Acapella One Cervical Spacer System is intended to be used with supplemental fixation (i.e., an anterior cervical plate).

Acapella One Cervical Spacer System implants are composed of PEEK Optima Grade LT1, Ti-6Al-4V, and tantalum. The body of the implant is composed of PEEK Optima Grade LT1 (ASTM 2026). The PEEK Optima Grade LT1 used in Acapella implants is manufactured using the same processes used to manufacture Exactech Octane-A implants (K082270).

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The material used to construct the anchors is titanium alloy Ti-6Al-4V per ASTM F136, which has a long history of safe and effective use in orthopedic implants.

The radiographic markers are composed of tantalum per ASTM F560, which also has a long history of safe and effective use in orthopedic implants.

The Acapella One Cervical Spacer System is accompanied by a complete instrumentation system to assist the surgeon in the implantation of the device.

Indications for Use
The Exactech Acapella One Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Exactech Acapella One Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following device characteristics:

- *Indications for Use*
  The proposed Acapella One Cervical Spacer System and predicate LDR ROI-C have similar indications for use statements.
- *Materials*
  Both proposed Acapella One Cervical Spacer System and predicate LDR ROI-C devices are composed of similar biocompatible materials conforming to recognized industry standards for permanent implants.
- *Design Features/Functions*
  Proposed Acapella One Cervical Spacer System and cited predicate devices share similar basic design features and functions.
- *Dimensions*
  Proposed Acapella One Cervical Spacer System devices are dimensionally similar to cited predicate devices.
- *Sterilization*
  Proposed Acapella One Cervical Spacer System devices and cited predicate devices are provided sterile for single use only.
- *Performance specifications*
  Mechanical testing confirmed Acapella One Cervical Spacer System devices demonstrated equivalent performance to cited predicates under the same test conditions.

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Non-Clinical Testing

The following tests were performed to demonstrate Acapella One Cervical Spacer System devices function as intended and are substantially equivalent to cited predicates:

Table 1: Acapella One Testing

Test	Standard
Static Compression	F2077
Static Compression Shear	F2077
Static Torsion	F2077
Static Torsion	F2077
Subsidence – Anchors Deployed	F22674
Subsidence – Anchors Not Deployed	F22674
Expulsion – Anchors Deployed	N/A
Expulsion – Anchors Not Deployed	N/A
Dynamic Compression	F2077
Dynamic Compression Shear	F2077
Dynamic Torsion	F2077
Wear	F1877

Substantial Equivalence Conclusion

The proposed Acapella One Cervical Spacer System has the same intended use, similar Indications for Use, the same technological characteristics, and the same principles of operation as the Exactech Octane-C, US Spine Phantom Plus, and LDR ROI-C Cervical Cage systems. In addition, proposed Acapella One implants are made from the same materials as predicate Exactech Octane-A devices. Information provided in this submission shows the proposed Acapella One Cervical Spacer System is substantially equivalent to the cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Exactech, Incorporated
Mr. Patrick Hughes
Senior Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K132582
Trade/Device Name: Exactech® Acapella® One Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: January 14, 2014
Received: January 15, 2014

Dear Mr. Hughes,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132582

Device Name
Exactech® Acapella® One Cervical Spacer System

Indications for Use *(Describe)*
The Exactech Acapella One Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Exactech Acapella One Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
FDA
Division of Orthopedic Devices

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